NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEBELA INTERNATIONAL LIMITED, Plaintiff, v. ACTAVIS LABORATORIES FL, INC., ACTAVIS PHARMA, INC., ANDRX CORP, and ACTAVIS, INC., Defendants.	Civil Action No.: 14-6414 (CCC) (JBC) (consolidated with 15-6225) **OPINION**
SEBELA INTERNATIONAL LIMITED, Plaintiff, v. PRINSTON PHARMACEUTICAL INC., SOLCO HEALTHCARE U.S. LLC, and HUAHAI U.S. INC., Defendants.	Civil Action No.: 14-7400 (CCC) (JBC) (consolidated with 15-5308)

CECCHI, District Judge.

I. INTRODUCTION

This matter comes before the Court upon the application of Plaintiff Noven Therapeutics, LLC ("Noven")[1] and Prinston Pharmaceuticals, Inc., Solco Healthcare U.S., LLC, and Huahai US Inc., Defendants in Civil Action No. 14-7400, and Actavis Laboratories FL, Inc., Actavis Pharma,

[1] Following briefing and oral argument, on September 20, 2016, this Court granted Noven's motion to substitute Sebela International Limited as Plaintiff and dismiss Noven Therapeutics, LLC. Case No. 14-6414, ECF No. 155; Case No. 14-7400, ECF No. 121.

Inc., Andrx Corp., and Actavis, Inc., Defendants in Civil Action No. 14-6414, (collectively "Defendants"), for claim construction, pursuant to Local Patent Rule 4.5. The parties submitted their Joint Claim Construction and Prehearing Statement on November 19, 2015, opening briefs were filed on December 16, 2015, Pl.'s Opening Br., Case No. 14-6414, ECF No. 81, Case No. 14-7400, ECF No. 56; Defs.' Opening Br., Case No. 14-6414, ECF No. 82, Case No. 14-7400, ECF No. 57, and responsive briefs were filed February 4, 2016, Pl.'s Reply Br., Case No. 14-6414, ECF No. 88, Case No. 14-7400, ECF No. 61; Defs.' Reply Br., Case No. 14-6414, ECF No. 89, Case No. 14-7400, ECF No. 60. The parties presented their arguments at a *Markman* hearing on August 9, 2016. Limited supplemental claim construction briefing was completed on August 17, 2016. Pl.'s Suppl. Br., Case No. 14-6414, ECF No. 144, Case No. 14-7400, ECF No. 114; Defs.' Suppl. Br., Case No. 14-6414, ECF No. 143, Case No. 14-7400, ECF No. 113. Subsequently, the parties entered a stipulation, removing from contention some of the contested terms. Case No. 14-6414, ECF No. 175; Case No. 14-7400, ECF No. 134. Having considered the parties' written submissions and oral arguments, the Court sets forth its construction of the disputed terms below.

II. BACKGROUND

A. Procedural Background

These two consolidated patent infringement actions were brought by Plaintiffs in connection with each Defendant's filing of an Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Act and have proceeded on parallel tracks. Plaintiffs assert four patents, U.S. Patent Nos. 5,874,447 (the "'447 patent"), 7,598,271 (the "'271 patent), 8,658,663 (the "'663 patent"), and 8,946,251 (the "'251 patent") (collectively, the "patents-in-suit").

Currently before the Court are the parties' disputes over the construction of two claim terms. The disputed claim terms are found in the '271 patent and the '251 patent. They are:

- Crystalline paroxetine methanesulfonate having the following IR peaks: 531,

546, 777, 838, 931, 962, 1038, 1100, 1169, 1208, 1469, 1500, 1515, 1615, 2577, 2869, 2900, 3023

- a dosage form of paroxetine

B. Scientific Background

The patents-in-suit pertain to a compound known as paroxetine and the compound's uses. Paroxetine has been identified as having pharmaceutical uses, including as an antidepressant and, as claimed in the patents-in-suit, as a drug for treating thermoregulatory dysfunction. *See, e.g.*, '251 Patent at 1:51-58. Paroxetine can form a variety of salts, including paroxetine mesylate, also known as paroxetine methanesulfonate. *See, e.g.*, '447 patent 1:27-33.

Several of the patent claims at issue relate to different chemical forms of paroxetine and the arrangement of the molecules therein. When the molecules are arranged in an ordered, repeating, regular pattern, they are said to be in a crystalline form. *See, e.g.*, Declaration of Dr. Robin D. Rogers ("Rogers") ¶ 26, Case No. 14-6414, ECF No. 82-1, Case No. 14-7400, ECF No. 57-31; Declaration of Allan S. Myerson, Ph.D. ("Myerson") ¶ 38, Case No. 14-6414, ECF No. 81-1, Case No. 14-7400, ECF No. 56-1. In contrast, when the molecules are not in an ordered array, they are said to be in an amorphous form. Rogers ¶ 27; Myerson ¶ 40. Certain molecules have more than one repeating pattern, or crystalline form, into which they can be arranged. Each of the crystalline forms is referred to as a polymorph. Rogers ¶ 30; Myerson ¶¶ 43-44. Although made up of the same constituent molecules, polymorphs can have different physical and chemical properties that can be pharmaceutically significant. When a compound has only one crystalline form, it is said to be monomorphic. Defs.' Opening Br. 5; Myerson ¶ 43.

Crystalline forms may be characterized and described using infrared ("IR") spectroscopy. Rogers ¶ 41; Myerson ¶¶ 51-52. IR spectroscopy involves shining IR radiation at a sample of the compound. Certain frequencies of radiation are absorbed by the sample as they interact with the

compound. Which frequencies are absorbed depends on the properties of the sample, including the crystalline structure. When the absorption is plotted, peaks are observed at those frequencies where the light was absorbed by, and therefore did not pass through, the sample. *See* Rogers ¶¶ 42-43; Myerson ¶ 51. These peaks can be used to characterize the crystalline form. *See* Rogers ¶¶ 41; Myerson ¶ 54.

III. LEGAL STANDARD

Claim construction is a matter of law for the Court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

The Court begins a claim construction analysis by examining the intrinsic evidence, which includes the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). If the claim term remains unclear or ambiguous after examining the intrinsic evidence, the Court may turn to extrinsic evidence, *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed. Cir. 1995), which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980.

"A claim construction analysis must begin and remain centered on the claim language itself." *Innova*, 381 F.3d at 1116. "[I]t is that language that the patentee chose to use to particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention." *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (internal quotation marks omitted). The claims themselves and the context in which a term is used within

the claims can "provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. In addition, other claims of the patent may be useful in construing a claim term, as "claim terms are normally used consistently throughout the patent." *Id.* Similarly, claims that differ from each other may provide insight into how a term should be read. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991).

"The claims, of course, do not stand alone. Rather, they are part of a fully integrated written instrument" called the "specification." *Phillips*, 415 F.3d at 1315. The Federal Circuit has said that "claims must be read in view of the specification." *Markman*, 52 F.3d at 978. For this reason, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582. Therefore, after examining the claims, "it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Vitronics*, 90 F.3d at 1582. "For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979.

Finally, the Court should also examine the prosecution history. *Phillips*, 415 F.3d at 1317. The prosecution history is the complete record of the proceedings before the United States Patent and Trademark Office ("USPTO"), and "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*; *see also Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013) (noting that the district court was correct in relying on prosecution statements when the specification contained no reference to the disputed term).

There is a heavy presumption that a claim term conveys its ordinary and customary meaning, which "is the meaning that the term would have to a person of ordinary skill in the art[2] in question at the time of the invention." *Phillips*, 415 F.3d at 1313. But a patentee may overcome this presumption and choose "to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999); *see also Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000); *Markman*, 52 F.3d at 979-80.

"[I]deally there should be no 'ambiguity' in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history." *Markman*, 52 F.3d at 986. However, if there remains ambiguity, the Court may consult extrinsic evidence. Extrinsic evidence is generally "less significant than the intrinsic record in determining the legally operative meaning of disputed claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). In addition, extrinsic evidence ordinarily should not contradict intrinsic evidence. *Phillips*, 415 F.3d at 1322-23. Therefore, extrinsic evidence must be viewed within the context of intrinsic evidence. *Id.* at 1319.

Consistent with the law of claim construction as discussed above, this Court will first look to the language of the disputed claim term itself in the context of the claim in which it appears as well as the other claims in the patent. The Court will then look to the patent specification and read the claim in view of the specification. Next, the Court will look to the prosecution history to determine whether and how the patentee understood the invention. Finally, to the extent necessary, the Court will look to the extrinsic evidence (such as expert declarations) to resolve any remaining

[2] In this Opinion, the Court will refer to a person of ordinary skill in the art as a "POSA." This term includes all iterations of this concept, such as "a person having ordinary skill in the art," "one of ordinary skill in the art," etcetera.

ambiguities. The Court will view the expert declarations within the context of the intrinsic evidence.

IV. DISCUSSION – '271 PATENT CLAIM 1

On October 6, 2009, the USPTO issued United States Patent No. 7,598,271, entitled "Crystalline paroxetine methane sulfonate." During prosecution, the application that gave rise to the '271 patent was the subject of an interference proceeding before the Board of Patent Appeals and Interferences ("BPAI") at the USPTO, in which the BPAI sought to resolve which inventor first invented the invention of the '271 patent. The BPAI ruled in favor of the applicants of the '271 patent. Case No. 14-7400, ECF No. 56-6; Case No. 14-6414, ECF No. 81-6.

The '271 patent has only one claim, which claims: "Crystalline paroxetine methanesulfonate having the following IR peaks: 531, 546, 777, 838, 931, 962, 1038, 1100, 1169, 1208, 1469, 1500, 1515, 1615, 2577, 2869, 2900, 3023." '271 Patent at 12:61-65. The parties have requested that this term be construed in its entirety. The parties' proposed constructions for this claim term are as follows:

Claim	Plaintiff's Proposed Construction	Defendants' Proposed Construction
'271 Patent Claim 1	Plain and ordinary meaning of a specific form of crystalline paroxetine methanesulfonate, i.e., the only known crystalline (solid form characterized by a regular, ordered arrangement of particles) solid form of paroxetine methanesulfonate.	Crystalline paroxetine methanesulfonate (*i.e.*, paroxetine methanesulfonate in a solid form characterized by a regular, ordered arrangement of particles) having all of the recited IR peaks.

The Court rejects the parties' proposed constructions and instead adopts the plain and ordinary meaning of the term as set forth below.

A. The Court's Construction

The ordinary and customary meaning of Claim 1 of the '271 patent is the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention."

Phillips, 415 F.3d at 1313. "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.* A POSA would undoubtedly be aware that IR spectroscopy is a technique prone to variability, and therefore, a POSA reading the '271 patent would understand that the listed values in Claim 1 are subject to a margin of error or experimental error, even absent an express indication. *See, e.g.*, *Eisai Co. v. Glenmark Pharm., Ltd.*, No. CV 13-1279-LPS, 2015 WL 1228958, at *7-8 (D. Del. Mar. 17, 2015) (holding that while "the claims and specification are silent on the matter of measurement error . . . a person of ordinary skill's understanding of the term XRPD would include the expected error associated with the measurement being used"); *Takeda Pharm. Co. v. Handa Pharm., LLC*, No. C-11-00840 JCS, 2012 WL 1243109, at *12 (N.D. Cal. Apr. 11, 2012) (same).

Read in light of the specification, the claim language indicates that what is claimed is a particular form of crystalline paroxetine mesylate that when subjected to IR spectroscopy produces a spectrum with peaks corresponding to the listed peaks. A POSA would undoubtedly be aware that IR spectroscopy is a technique prone to variability, and understand that the listed peaks are not necessarily precise measurements, but might instead be subject to an error range.

B. Plaintiff's Proposed Construction Improperly Reads Out Claim Limitations

Plaintiff argues that the peaks in Claim 1 of the '271 patent are simply one means of characterizing what is claimed and the claim should be interpreted to cover the underlying compound, rather than being limited "to the *means* by which the compound was characterized (*i.e.*, a list of singular IR peaks)." Pl.'s Opening Br. 11. As there is only one known crystalline form of paroxetine mesylate, Plaintiff argues the claim must cover that. *Id.* Plaintiff characterizes its construction as the "plain and ordinary" meaning. However, claim construction "must begin and remain centered on the claim language itself," *Innova*, 381 F.3d at 1116, and Plaintiff's proposed construction deviates from the written language of the claim in two significant and related ways:

(1) it does not capture the listed IR peaks, and (2) it specifies that the claimed form of paroxetine mesylate is "the only known crystalline solid form of paroxetine [mesylate]," which Plaintiff acknowledges does not have an IR spectrum that includes each and every peak in the claim. Pl.'s Opening Br. 12.

Plaintiff argues that these deviations from the language of the claim are justified as the IR peaks listed in the claim are merely a means of describing the crystalline form of paroxetine mesylate invented and not the "invention itself." *See* Pl.'s Opening Br. 10-11. Instead, Plaintiff suggests that the "invention itself" is the crystalline form of paroxetine mesylate. *See* Pl.'s Opening Br. 10-11. Implicit in Plaintiff's argument is the idea that the "thing that is patented" is necessarily the same as what the inventor invented. *See* Pl.'s Opening Br. 10-11; Pl.'s Reply Br. 7 ("As noted in Noven's opening brief, the purpose of claim construction is to ascertain the 'thing that is patented,' not the 'formula' or other 'means of describing a compound,' neither of which is 'the invention itself.'"). The Court is not persuaded by this argument.

The scope of a patent claim is not necessarily coterminous with what the inventor discovered or was entitled to claim as its "invention." *See Bayer CropScience AG v. Dow AgroSciences LLC*, 728 F.3d 1324, 1332 (Fed. Cir. 2013) (noting that a patentee may fail to protect its "core invention" where the claims as written do not cover that invention). The Patent Act, as it was in effect at the time the '271 patent was applied for and issued, required that a patent "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the *applicant*[3] *regards as his invention*." 35 U.S.C. § 112 (emphasis added). "Under this provision of § 112, the scope of the subject matter is governed not

[3] Effective September 2012, the word "applicant" was replaced with the phrase "inventor or a joint inventor." This change would not affect the Court's analysis.

by the examiner's conception of the 'invention' but by that 'which the applicant regards as his invention.'" *In re Wolfrum*, 486 F.2d 588, 591 (C.C.P.A. 1973); *accord In re Zletz*, 893 F.2d at 321-22 (Fed. Cir. 1989). Therefore, a patent's claims may be more limited than the underlying invention that the patentee may have been able to protect. *See Bayer CropScience AG*, 728 F.3d at 1332 ("[I]t is hardly unknown for a patentee with an invention that could be protected to fail in securing such protection by bad choices in claim drafting."). This correlates with the fundamental principle that the claims of a patent serve an important public notice function, defining the scope of the patentee's property rights. *See id.* at 1328.

The cases Plaintiff cites in support of its position all involve circumstances where the central question for the court was what underlying invention the patentee *may have* been entitled to claim. *See Cubist Pharm., Inc. v. Hospira, Inc.*, 805 F.3d 1112, 1117 (Fed. Cir. 2015) (assessing appropriateness of certificate of correction), cert. denied, 136 S. Ct. 2393; *Regents of Univ. of New Mexico v. Knight*, 321 F.3d 1111, 1122 (Fed. Cir. 2003) (determining inventorship); *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963) (determining patentability during examination). Here, the relevant question is what the inventors did claim.

Plaintiff's position is also unsupported by the language of the claim and the language of the specification. Neither the claim nor the rest of the specification suggests that there is only one known crystalline solid form of paroxetine mesylate. Instead, the specification expressly notes that the compounds of the invention "could exist in other crystalline or polymorph modifications which may differ from those as described herein."[4] '271 patent at 11:32-37. Plaintiff's arguments

[4] Further, read as a whole, the claim implies that there may be multiple crystalline solid forms of paroxetine mesylate given the inclusion of a list of identifying peaks. *C.f. Phillips*, 415 F.3d at 1314 ("[T]he claim in this case refers to 'steel baffles,' which strongly implies that the term 'baffles' does not inherently mean objects made of steel.").

instead rely significantly on the prosecution history of the '271 patent. *See* Pl.'s Opening Br. 11-18; Pl.'s Reply Br. 7-10; Pl.'s Suppl. Br. 2-3.

Plaintiff's argument that claim 1 should be construed to mean "the only known crystalline solid form of paroxetine mesylate" because that is "the same scope the BPAI afforded it," Pl.'s Opening Br. 13-16, ignores a crucial difference between the way claim scope is determined in USPTO proceedings, including interference proceedings before the BPAI, and the way claim scope is determined in litigation over validity and infringement. During examination, and in interference proceedings before the BPAI, claims are given their "broadest reasonable construction."[5] 37 C.F.R. § 41.200. This is different from the "mode of claim interpretation that is used by courts in litigation, when interpreting the claims of issued patents in connection with determinations of infringement or validity." *In re Zletz*, 893 F.2d at 321. This Court is required to apply the analytical framework applied in *Phillips*. Because these two frameworks serve different purposes and define the scopes proposed and issued claims differently, Plaintiff's argument that "the interference record of the prosecution history reveals that Noven's construction is commensurate with the scope afforded the instant claim by the BPAI" holds little weight.

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[5] Under the broadest reasonable construction standard, "[w]hen the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). During these proceedings, it is understood that the claims are a work in progress, and "during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed." *Id.* at 321 (citations omitted); *see also In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004) ("The 'broadest reasonable interpretation' rule recognizes that 'before a patent is granted the claims are readily amended as part of the examination process.' Thus, a patent applicant has the opportunity and responsibility to remove any ambiguity in claim term meaning by amending the application." (citations omitted)); *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997) ("It would be inconsistent with the role assigned to the PTO in issuing a patent to require it to interpret claims in the same manner as judges who, post-issuance, operate under the assumption the patent is valid. The process of patent prosecution is an interactive one."); MPEP § 2111 (discussing the application of the broadest reasonable interpretation standard and citing cases).

The inventors of the '271 patent had numerous ways of describing what they regarded as their invention. They chose to claim a crystalline form of paroxetine mesylate by reference to a set of IR peaks. The Court sees no reason to read the peaks out of the claim.[6] *See Bayer CropScience AG*, 728 F.3d at 1332. As such, the IR peaks in the claim language will be afforded the appropriate weight.

C. Defendants' Proposed Construction Is Too Narrow in Light of Scientific Realities

The Court also does not accept Defendants' proposed construction. Defendants' assert that under their proposed claim construction every peak must be present at precisely the listed value with no leeway for a range of error.[7] *See, e.g.*, Defs.' Suppl. Br. 1-8. This reads the claim too narrowly in light of the understanding and knowledge of a POSA.

Unlike in the cases cited by Defendants for the proposition that an error range should not be read into the claim, here the specification of the '271 patent does not indicate that any special meaning has been assigned to the disputed claim term. In contrast, in *Takeda Pharmaceuticals Co. v. Zydus Pharmaceuticals USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014), the patent claim covered orally disintegrable tablets comprising "fine granules having an average particle diameter of 400 μm or less," *id.* at 1362. The specification made clear that the size value given in the disputed term was intended to serve as a clear dividing line between "conventional" granules and "fine" granules, and was important to achieving the patent's objective of avoiding a feeling of roughness

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[6] Similarly, while claims should generally be read to cover the preferred embodiment, *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1311 (Fed. Cir. 2014), here, the Court's construction is consistent with the embodiment disclosed in the specification. *See* '271 patent at 10:43-44.

[7] The Court notes the Defendants' arguments at times seem to conflate the concepts of "error" as that term is used in the general sense and "error" as that term is used technically when describing the concepts of statistical or experimental error. *See, e.g.*, Defs.' Suppl. Br. 8.

in the patient's mouth upon disintegration. *Id.* at 1364. Similarly, in *Novartis Pharmaceuticals, Corp. v. Wockhardt USA LLC*, No. 12-CV-3967 SDW MCA, 2014 WL 2861209 (D.N.J. June 24, 2014), the specification described the infusion rate in the claim as "precise[]." In each case, the specification indicated the importance of the exact value. Here, there is no suggestion in the '271 patent that peak values given in claim 1 are intended to be interpreted any more precisely than a POSA normally would interpret them.

This is further supported by the prosecution history of the '271 patent. During the interference proceeding, Franciscus Benneker, a named co-inventor of the '271 patent, submitted a declaration describing the process used to identify the peaks claimed in the '271 patent. *See* Decl. of Allan S. Myerson, Ph.D., Ex. R, Case No. 14-7400, ECF No. 56-5, Case No. 14-6414, ECF No. 81-5 ("Benneker Decl."). Dr. Benneker's Declaration indicates that the values listed in claim 1 of the '271 patent were calculated by hand from a spectrum generated by the IR analysis of a sample he perpared. Benneker Decl. ¶¶ 5, 7-9. A POSA reviewing the prosecution history, would therefore, understand that the values listed in claim 1 are subject to experimental error or a range of error.

V. DISCUSSION – THE '251 PATENT

United States Patent No. 8,946,251, issued February 3, 2015, claims methods of treating a patient suffering from a thermoregulatory dysfunction associated with menopause by administering paroxetine. Disputed claims 1, 2, 4, and 9-10 of '251 patent contain the phrase "a dosage form of paroxetine." The parties have requested this term be construed as follows:

Claim	Claim Term	Plaintiff's Proposed Construction	Plaintiff's "Compromise" Construction[8]	Defendants' Proposed Construction
'663 Patent Claims 1, 2, 4, 9-10	"a dosage form of paroxetine"	Plain and ordinary meaning, *i.e.*, orally ingested forms of paroxetine	Paroxetine or a pharmaceutically acceptable salt thereof in any of the physical forms in which paroxetine was produced and dispensed as of the effective filing date of the '251 patent	Paroxetine or a pharmaceutically acceptable salt thereof in any of the physical forms in which drugs can be produced and dispensed

The primary dispute over this term is whether "a dosage form of paroxetine" is limited to orally ingested forms of paroxetine.[9] The Court finds the term is broader, and Plaintiff's initial proposed construction and "compromise proposal" are both unduly limited. In contrast, the Court finds Defendants' proposed construction is too broad, as the claim is limited on its face to "dosage form[s] of paroxetine." Therefore, the claim should not be read to cover dosage forms other than those in which paroxetine can be produced.

Contrary to Plaintiff's repeated assertions, nothing suggests the "plain and ordinary meaning" of "a dosage form of paroxetine" means "*orally ingested* forms of paroxetine." *C.f. King Pharm., Inc. v. Purdue Pharma, L.P.*, 718 F. Supp. 2d 703, 708-09 (W.D. Va. 2010) (holding the ordinary and customary meaning of "dosage form" is "the physical form of a drug product"). Further, nothing in the claim language limits "a dosage form" to "orally ingested forms."

The specification of the '251 patent likewise does not limit the phrase "a dosage form of paroxetine" to orally ingested forms. To the extent Plaintiff argues that its construction should be adopted because "[t]he only dosage forms of paroxetine discussed in the '251 patent

[8] Pl.'s Opening Br. 24-25.

[9] Although Plaintiff's proffered "compromise construction" does not expressly state that the "compromise construction" is limited to orally ingested forms of paroxetine, Plaintiff's arguments make clear that Plaintiff believes it to be so limited. *See* Pl.'s Reply Br. 16.

specification . . . are oral dosage forms," or because "[t]he only dosage forms of paroxetine discussed in . . . the patents and publications cited [in the '251 patent specification] that discuss specific dosage forms of paroxetine, are oral dosage forms," this argument falls short. The Federal Circuit "has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Liebel-Flarsheim Co.*, 358 F.3d at 906. Instead "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Id.* at 906 (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)). Further, it is well established that "[w]hile [the Court] reads claims in view of the specification, of which they are a part, we do not read limitations from the embodiments in the specification into the claims." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)), *cert. denied*, 135 S. Ct. 719 (2014).

To support its position that the term "a dosage form of paroxetine" should be limited to orally ingested forms of paroxetine, Plaintiff first relies on language in the specification that discusses dosing at "less than an antidepressant effective dosage of paroxetine." Plaintiff argues that a POSA would understand that because orally ingested dosage forms of paroxetine were used for treating depression, the doses described in the patent were orally ingested forms. Pl.'s Opening Br. 26-27. Similarly, Plaintiff argues that a POSA reading the specification "in the context of the Stearns paper cited in the 'Background Of The Invention' section . . . would have recognized and known that Stearns . . . reports a study that used orally ingested paroxetine hydrochloride . . . , and thus, would likewise have understood that the disclosed doses in the '251 Patent of 'up to 9.5

mg/day,' including the 7.5 mg/day dose recited in the '251 patent claims, were less than the lowest, 10 mg/day, orally ingested dose used in Stearns 2000." Pl.'s Opening Br. 27. Plaintiff additionally notes that the publications reporting the testing of antidepressants in human patients described in the Background section of the patent each used orally ingested forms, Pl.'s Opening Br. 27-28, and that the Background section states "[v]arious pharmaceutical dosage forms are known," and lists five patents, each of which Plaintiff argues discloses only orally ingested forms of paroxetine, Pl.'s Opening Br. 29.

Defendants note, however, that the patent states that "various pharmaceutical dosage forms are known." Defs.' Opening Br. 22 (quoting '251 patent at 3:13-16)). They further observe that the patents cited in the background section of the '251 patent broadly indicate that paroxetine is "appropriate for any type of pharmaceutical [dosage] form," and those patents refer to specific non-oral dosage forms, including injections, infusions, topical, and suppository forms. Defs.' Opening Br. 23.

The parties dispute the extent to which these publications and patents disclose other dosage forms of paroxetine. Taken collectively, Plaintiff's arguments *at best* show that the embodiments of the invention disclosed in the '251 specification all use orally ingested forms of paroxetine. This is insufficient to support Plaintiff's proposed construction, as Plaintiff has not shown that "the patentee has demonstrated a clear intention *to limit* the claim scope using 'words or expressions of *manifest exclusion or restriction.*'" *Liebel-Flarsheim Co.*, 358 at 906. The Court, therefore, rejects Plaintiff's initial proposed construction as it improperly restricts the term "a dosage form of paroxetine" to orally ingested forms.

The Court similarly rejects Plaintiff's "compromise proposal," which limits "a dosage form of paroxetine" to "any of the physical forms in which paroxetine *was* produced and dispensed as

of the effective filing date of the '251 patent." This construction improperly limits the scope of the claim to dosage forms that were in fact being made and used at the time of filing. Federal Circuit "case law allows for after-arising technology to be captured within the literal scope of valid claims that are drafted broadly enough." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1371–72 (Fed. Cir. 2008) (dicta); *accord SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 878 (Fed. Cir. 2004). Here, as in *SuperGuide Corp.*, 358 F.3d at 878, "[t]he claim language does not limit the disputed phrases to any particular type of technology." Further, it appears undisputed that a POSA was aware at the time of filing that there were numerous "dosage forms" available for use generally.[10] *See id.* at 879. The term "a dosage form of paroxetine" is, therefore, broad enough to capture after-arising dosage forms of paroxetine and is not limited to orally ingested forms, and properly captures paroxetine or a pharmaceutically acceptable salt thereof in any of the physical forms in which paroxetine can be produced and dispensed.

VI. CONCLUSION

The Court construes the disputed claim terms of the '271, '663, and '251 patents as follows:

Claim	Disputed Claim Term	Court's Construction
'271 Patent Claim 1	"Crystalline paroxetine	Plain and ordinary meaning, *i.e.*, a particular form of crystalline paroxetine mesylate,

[10] Plaintiff attempts to distinguish *SuperGuide*, stating "*Superguide* is inapposite, because there it was 'indisputable' that alternatives were known in the art 'during the pendency of the . . . patent application.' [*SuperGuide*] at 878." Pl.'s Suppl. Br. 10. In *SuperGuide*, the Federal Circuit addressed whether the term "regular received television signal" must be limited to analog signals because "no televisions existed as of [the filing] date that could receive digital signals." *SuperGuide*, 358 F.3d at 876-78. The court rejected this argument, as it was "indisputable" that "video data *could be* communicated in either analog or digital form." *Id.* at 879 (emphasis added). The court did not find that *television* signals, to which the claim was specifically directed, in fact, existed in digital form. *See id.* at 879 n.6. Here, Plaintiff does not appear to argue that paroxetine cannot be made in non-oral dosage forms. Rather, Plaintiff argues that the only known forms are oral dosage forms, the very argument rejected by the Federal Circuit in *SuperGuide*. *See also Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, No. C 05-04158MHP, 2007 WL 5787309, at *11 (N.D. Cal. Nov. 27, 2007).

	methanesulfonate having the following IR peaks: 531, 546, 777, 838, 931, 962, 1038, 1100, 1169, 1208, 1469, 1500, 1515, 1615, 2577, 2869, 2900, 3023"	which when subjected to IR spectroscopy produces a spectrum with peaks corresponding to the listed peaks
'251 Patent Claims 1, 2, 4, 9-10	"a dosage form of paroxetine"	Paroxetine or a pharmaceutically acceptable salt thereof in any of the physical forms in which paroxetine can be produced and dispensed

An appropriate Order accompanies this Opinion.

Dated: November 21, 2016

HON. CLAIRE C. CECCHI
United States District Judge